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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,122	01/29/2002	Philip B. Sample	00167-455001	3500

7590  
JOEL R. PETROW  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, TN 38116

11/13/2008

EXAMINER
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SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3775

MAIL DATE	DELIVERY MODE
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11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/058,122	<b>Applicant(s)</b> SAMPLE, PHILIP B.	
	<b>Examiner</b> Richard Shaffer	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26,37,38,41,42,44-72,74,75 and 77-86 is/are pending in the application.
- 4a) Of the above claim(s) 4,7-10,20,22 and 38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 72,74,75,77-79,81 and 82 is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,11-19,21,23-26,37,41,42,44-71,80 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Applicant's amendments and arguments filed on March 21<sup>st</sup>, 2008 are acknowledged by the examiner. The previous 35 U.S.C. 112, first paragraph rejections have been overcome and are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 11-19, 21, 23-26, 42, 44-46, 79 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites, "...wherein the coupling of the cutter to the outer member restrains the cutter from rotating at the same rate as the inner member." The outer member merely holds the cutter at a desired orientation, it does not affect the rotational speed of the cutter, further there is no support that the rates are the same or different between the cutter and inner member.

All dependent claims have been rejected for including the new matter limitation through dependence.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 11-19, 21, 23-26, 37, 41, 42, 44-71, 77-79, 83-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin et al (WO 92/08416).

Hamlin et al disclose (**Figures 3-12**) a cutting instrument comprising: an outer member (**46, 30 and 22 together**) having a spherical terminal end housing a cutter (**62**); the cutter comprises a spherical portion; the terminal end further defines an opening (**50**); the cutter (**62**) having an opening (**64**) and a circumferentially located plurality of teeth (**66**); the outer member includes a first and second arc-shaped chambers to receive shafts (enlarge portion **56** is the second shaft and the portion containing the plurality of teeth is the first shaft) of the cutter (**62**); an inner member (**70**) having a hollow passage capable of removing cut tissue through it; the inner member having a plurality of teeth (**78**) for engaging the teeth (**66**) at a perpendicular angle (**Page 3, Lines 28-33**); and the inner member will rotate about a fixed axis causing the cutter to rotate about a perpendicular axis. The device of Hamlin et al is inherently capable of performing the intended functions of applicant's claimed device as well as anticipating applicant's product-by-process claims since applicant must make a showing that one would not be able to form the device of Hamlin et al in the manners claimed to overcome anticipation.

In regard to claim 1, the outer member restricts the cutter from rotating at the same rate along the central longitudinal axis of the inner member.

In regard to claim 37, the distalmost point of the outer member is still broad enough to encompass the portion the cutter extends through due to the lack of reference of proximal and distal. When in use, the portion that would be contacting tissue to be cut would be the opening, and therefore would be the distalmost point of use, or the distalmost point along a different axis, or the distalmost point of the device intended for tissue contact, etc.

In regard to claim 47, a cutting edge of the cutter intersects a longitudinal axis of the inner member due to a longitudinal axis merely being an axis **along** the major axis of a body. Therefore, it can be parallel to a central axis of the body such that it intersects the cutting edge of the cutter.

Claims 80 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Sastri (US Patent 5,630,826).

Sastri discloses (**Figures 1-6**) a device comprising: an outer member (**22**); an inner member (majority of **24**) received within the outer member having a passage; a cutter coupled to the inner member (end piece of **22** with cutting edge **34** as shown in **Figure 3**); rotation of the inner member causes “off-axis” movement of the cutter; off-axis in this case is relative to any axis not running along a longitudinal axis of the inner member and cutter; the cutter defining a second passage which is coaxially aligned during the off-axis movement.

***Allowable Subject Matter***

Claims 72, 74, 75, 77-79, 81 and 82 are allowed.

***Response to Arguments***

Applicant's arguments filed on March 21<sup>st</sup>, 2008 regarding the 35 U.S.C. 112, first paragraph rejections have been fully considered and are persuasive. The previous 35 U.S.C. 112, first rejections have been withdrawn. However, as stated in the current Office Action, the newly submitted amendments to claim 1 are deemed to include new matter.

Applicants arguments regarding the Michelson reference (US 2002/0058944) are also persuasive in view of the amendments and arguments submitted on March 21<sup>st</sup>, 2008, therefore the previous 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections citing Michelson have been withdrawn.

Applicant's arguments filed on March 21<sup>st</sup>, 2008 have been fully considered but they are not persuasive in view of the 35 U.S.C. 102(b) rejection as being anticipated by Hamlin et al. As pointed out in the current Office Action, the amendments to independent claims 1, 37 and 47 are deemed insufficient to define over the prior art due to the reasons already explained in the current Office Action.

***Conclusion***

Applicant's amendment of claim 80 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733